REMARKS

I. Introduction

The Office Action mailed June 29, 2009, has been carefully considered. Applicants gratefully acknowledge the courtesy of an interview on July 31, 2009, in which Applicant's representative, Minh-Quan Pham, the Examiner, and Supervisory Examiner Johann Richter discussed the claims and the cited reference (Doen et al.). It was agreed that it is possible to overcome the rejection by showing that the claimed rabeprazole sodium to alkaline compound ratio is not expected by one of ordinary skill in the art. The present Amendment is intended to be a complete response thereto and to place the case in condition for allowance.

II. Status of the Claims

Claims 1, 7-10, 12, and 16-18 are pending. Claims 2-6, 11, and 13-15 have been cancelled. Claims 1, 10, and 17 have been amended. Support for the amendment to claim 1 is found, *inter alia*, in the specification on page 5, sixth paragraph. Claims 10 and 17 have been amended to have antecedent basis in claim 1.

III. Summary of the Office Action

In the Office Action, the Examiner objected to the specification due to certain confusion in the table on page 7.

The Examiner also rejected the claims as follows:

1) claims 10 and 17 under 35 U.S.C. § 112, second paragraph, as lacking antecedent basis for "said excipient;" and

2) claims 1, 7-10, 11, and 16-18 under 35 U.S.C. § 103(a) as being obvious over Doen et al. (U.S. 2003/0191157).

IV. Arguments

Applicant respectfully traverses the rejections for the following reasons:

A. The specification is proper

The specification stands objected to. The Examiner alleges that the ratio of rabeprazole sodium to alkaline compound may have been miscalculated from the table on page 7. Applicants respectfully submit that there is no error here. 5% drug overage was added and quantity of Sodium hydroxide was calculated accordingly. The overages were added to take care of drug stability with a possibility of moisture variability amongst vials. Accordingly, no error was made in the calculation and the ratio is properly from the table as 1:0.359. Withdrawal of the objection is respectfully solicited.

B. The claims are not indefinite

Claims 10 and 17 stand rejected as lacking antecedent basis for "said excipient." Those claims have been amended to recite "said mannitol" instead, which has antecedent basis in claim 1. Therefore, the claims are not indefinite. Accordingly, Applicants respectfully request withdrawal of the rejection.

C. The claims are not obvious

Claims 1, 7-10, 11, and 16-18 stand rejected as being obvious over Doen et al. The Examiner alleges that although Doen et al. disclose a rabeprazole to alkaline compound ratio of 1:1, one of ordinary skill in the art would be motivated to increase this ratio because Doen et al. discloses that "the amount of strong alkali can be decreased." Office Action, page 7. Applicants

respectfully submit that the disclosure cited by the Examiner (Paragraph [0088] of Doen et al.) compares the invention of Doen et al. to the prior art, i.e., the formulation of Doen et al. already decreases the alkaline amount compared to its prior art formulations. The paragraph reads as follows:

> According to the present invention, the amount of the strong alkali can be decreased, and the solubility of the injectable composition can be improved with being substantially free from using a nonaqueous solvent (or a water-soluble organic solvent). Therefore, the present invention also discloses use of a strong alkali for producing the above injectable composition.

Thus, when compared to the prior art, Doen et al. have decreased to amount of "strong alkali" resulting a composition containing relatively low levels of the "strong alkali." Nevertheless, Doen et al. is only able to reduce the "strong alkali" amount to "preferably about 0.9 to 1.10 ... equivalents." Doen et al. do not teach further reducing the alkali amount to significantly below 0.9 to 1.10 equivalents (equal to the rabeprazole to alkaline compound ratio). If Doen et al. deem it essential to further reduce the "strong alkali" amount, they would not have disclosed the preferred "strong alkali" amount of "about 0.9 to 1.10" equivalents, which is much higher that the presently claimed ratio of 0.359 (alkaline compound to rabeprazole). Nowhere in the cited reference do Doen et al. attempt to lower the "strong alkali" amount to below 0.9 to 1.10 equivalents. Thus, Doen et al. cannot be reasonably read to suggest lowering the alkali content to below the specifically disclosed value.

Additionally, even if Doen et al. suggest decreasing the amount of "strong alkali," which Applicants deny, there is no rationale that one of ordinary skill in the art would arrive at the presently claimed rabeprazole to alkaline compound ratio or 1:0.359. Why would one of ordinary skill use any "strong alkali" at all, if as suggested by the Examiner it is desired to decrease its content? Why not just decrease it to 1:0.5 instead? Thus, there is no rationale to

arrive at the specific ratio of 1:0.359 instead of any other arbitrary number less than about 1:1. The only reason the Examiner is able to arrive at the ratio of 1:0.359 is from reading the present claims. That is clear hindsight reasoning where the Examiner has fallen "victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000) (internal quotation omitted).

Further, it is generally expected that the pH of a solution would decrease if the alkaline compound in that solution is decreased. The pH of the solution is important in maintaining the quality of the drug as disclosed by Doen et al. in paragraph [0006]:

> such injectable compositions are considerably needed as preventing pH of the injectable composition from decreasing upon producing and redissolving of the injectable composition, and as maintaining the quality of the injectable composition.

However, in the present invention, Applicants have unexpectedly discovered that it is possible to decrease the amount of the alkaline compound to a ratio of 0.359:1 (alkaline compound:rabeprazole) from the 1:1 ratio taught by Doen et al., without significantly reducing the pH of the solution, thereby, maintaining the drug quality. This discovery is unexpected and is not disclosed, suggested, or contemplated by Doen et al.

Therefore, for the reasons noted, the present invention is not obvious over Doen et al. within the meaning of 35 U.S.C. § 103. Accordingly, Applicants respectfully request withdrawal of the rejection.

V. Conclusion

Applicants have responded to the Office Action mailed December 11, 2008. All pending claims are now believed to be allowable and favorable action is respectfully requested.

In the event that there are any questions relating to this Amendment or to the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that the prosecution of this application may be expedited.

Please charge any shortage or credit any overpayment of fees to BLANK ROME LLP, Deposit Account No. 23-2185 (125139.0101). In the event that a petition for an extension of time is required to be submitted herewith and in the event that a separate petition does not accompany this response, Applicants hereby petition under 37 C.F.R. 1.136(a) for an extension of time for as many months as are required to render this submission timely.

Any fees due are authorized above.

Respectfully submitted,

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